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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,296	07/15/2003	Katsuro Tachibana	EKOS.8CP3DV1C3	7573

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EXAMINER	
BOCKELMAN, MARK	
ART UNIT	**PAPER NUMBER**
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/06/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/06/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/620,296	TACHIBANA ET AL	
	Examiner	Art Unit	
	Mark W. Bockelman	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10-24-03; 3-7-05; 5-15-06; 3-1-07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant's earliest priority date for disclosing ultrasound being used to activate a light activated drug in a microbubble is September 21, 1998, which is the filing date of Applicant's US Patent No. 6,176,842.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. USPN 5,277,913.

Thompson et al. teach a microbubble in the form of a liposome containing shell, a light activated drug and another therapeutic (column 3, lines 32-43; column 7, lines 21-26, 48-49). Examples of light activatable drugs provided with the liposome are shown in Table 1 at cols. 5-6, and include light activatable drugs which are also activatable ultrasonically, such as phthalocyanines, naphthalocyanines, chlorins, and bacteriochlorin as can be seen from applicant's specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Unger et al USPN 5,542,935 (alone or in view of (Umemura et al. "Sonochemical Activation of Hematoporphyrin: A potential Modality for Cancer Treatment" 1989 Untrasonics Symposium, IEEE (1989) pp 955-960 or "Synergystic Effect of Ultrasound and Hematoporphyrin on Sarcoma 180" Jpn. J. Cancer Res. Vol,1, pp304-308 (March 1990).

Unger teaches using ultrasound to rupture therapeutic-containing microspheres, thereby releasing the therapeutic into the patient's body (column 4, lines 31-37; column 7, lines 21-25). The microspheres may contain one or more therapeutic agents (column 26, lines 34-37), including hematoporphyrins and their derivatives (light activated drug) (col. 24, lns. 16, 54-55), wherein the therapeutics may be embedded in the wall of, encapsulated in, and/or attached to the microspheres (column 6, lines 56-59; column 23, lines 56-57). The microspheres may be liposomes (column 10, lines 33-51; column 20, lines 4-9; column 17, lines 30-31). Although Unger et al does not necessarily state the benefit of using ultrasound with the light sensitized liposomes, he inherently performs the same method as applicant. The secondary references demonstrating that the activation of the medicaments can be performed using the ultrasound.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. USPN 5277913 in view of Lawandy USPN 5,817,048.

Thompson teaches a microbubble in the form of a liposome containing shell, a light activated drug and another therapeutic (column 3, lines 32-43; column 7, lines 21-26, 48-49). The light activated drug may be coupled to the liposome shell, encapsulated within the liposome, or included in the media surrounding the liposome (column 3, lines 38-43; column 5, lines 21-23; column 7, lines 24-26, 53-54). Thompson does not specifically teach activating the light activatable drugs by ultrasound. This however is taught by Lawandy. Specifically, Lawandy teaches using ultrasound to activate light activatable therapeutic compounds (column 1, lines 46-48, 51-52, 56; column 2, lines 24-28). It would have been obvious to use ultrasound to activate the liposomes disclosed in Thompson, to improve activation of photosensitive therapeutic compounds and to provide a non-invasive way to activate such compounds, as stated in Lawandy at column 1, lines 26-33.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al USPN 5,542,935 in view of Thompson et al. USPN 5277913.

Unger does not disclose that the light activatable drug may be located in the medium surrounding the microbubble. Thompson discloses this at col. 7, lns. 24-26. It would have been obvious to provide light activatable drug in the medium surrounding the microbble disclosed in Unger depending on the characteristics of the therapeutic compounds selected to be delivered by the microbubble, and the location of those compounds relative to the microbubble.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al USPN 5,542,935 in view of Ragheb et al. USPN 6,096,070.

Unger teaches using ultrasound to rupture therapeutic-containing microspheres, thereby releasing the therapeutic into the patient's body (column 4, lines 31-37; column 7, lines 21-25). The microspheres may contain one or more therapeutic agents (column 26, lines 34-37), including hematoporphyrins and their derivatives (light activated drug) (column 24, lines 16, 54-55), wherein the therapeutics may be embedded in the wall of, encapsulated in, and/or attached to the microspheres (column 6, lines 56-59; column 23, lines 56-57). The microspheres in Unger may be delivered into a patient's blood vessels (column 32, lines 31-33, 37-40).

Unger does not specifically disclose that the other therapeutic provided with the microsphere is a thrombolytic agent. However, Ragheb teaches microencapsulating a bioactive compound in a microsphere such as a liposome (column 18, lines 17-20), and providing a plurality of bioactive compounds with such microspheres such as photodynamic therapy agents and thrombolytic agents (column 3, lines 45-48, 53-54; column 18, lines 3-5; column 8, lines 6-17). It would have been obvious to have encapsulated a thrombolytic agent as disclosed in Ragheb into the microspheres taught in Unger and deliver them into the patient's blood vessels by ultrasound as further discussed in Unger, to provide appropriate treatment for a patient in a manner consistent with the many examples disclosed in Unger.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached at 571 -272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWB

March 31, 2007